1.4.3	Patient Information Leaflet

Xylocaine Jelly 2%

lidocaine hydrochloride
Jelly

Composition
Active constituent:
1g Xylocaine jelly contains: Lidocaine hydrochloride 20 mg.

Pharmaceutical form
Xylocaine jelly is a clear to almost clear, slightly coloured jelly. The vehicle of the active ingredient consists of water thickened with hydroxypropyl methylcellulose. Xylocaine jelly contains methyl parahydroxybenzoate and propyl parahydroxybenzoate.

Therapeutic indications
Xylocaine jelly is indicated as a surface anaesthetic and lubricant for:
- The male and female urethra during cystoscopy, catheterization, exploration by sound and other endourethral procedures.
- Nasal and pharyngeal cavities in endoscopic procedures such as gastroscopy and bronchoscopy.
- During proctoscopy and rectoscopy.
- Tracheal intubation.

Symptomatic treatment of pain in connection with cystitis and urethritis.
To relieve pain after circumcision in children.

Posology and method of administration
Xylocaine jelly 2% provides prompt and profound anaesthesia of mucous membranes, giving effective anaesthesia of long duration (approx. 20-30 min). Anaesthesia usually occurs rapidly (within 5 min depending upon the area of application).

As with any local anaesthetic, the safety and effectiveness of lidocaine depend on the proper dosage, the correct technique, adequate precautions and readiness for emergencies.

The following dosage recommendations should be regarded as a guide. The clinician's experience and knowledge of the patient's physical status are of importance in calculating the required dose.

Absorption from mucous membranes is variable but especially high from the bronchial tree. The absorption of lidocaine jelly from the nasopharynx is usually lower than with other lidocaine products. Blood concentrations of lidocaine after instillation of the jelly in the intact urethra and bladder in doses up to 800 mg are fairly low and below toxic levels.

Debilitated or elderly patients, children over 12 years of age, acutely ill patients
or patients with sepsis should be given doses commensurate with their age, weight and physical condition.

In children under the age of 12 years the dose should not exceed 6 mg/kg.

No more than four doses should be given in a 24 hour period.

Urethral anaesthesia
Surface anaesthesia of the male adult urethra: for adequate analgesia in males
20 ml (= 400 mg lidocaine hydrochloride) jelly is required. The jelly is instilled slowly until the patient has a feeling of tension or until almost half the tube (10 ml
= 200 mg lidocaine hydrochloride) has been emptied. A penile clamp is then applied for several minutes at the corona, after which the rest of the jelly is instilled.

When anaesthesia is especially important, e.g. during sounding or cystoscopy, a larger quantity of jelly (e.g. 30-40 ml) may be instilled in 3-4 portions and allowed to act for 10 minutes before insertion of the instrument. The jelly instilled into the bladder is also effective for procedures in this region.

Surface anaesthesia of the female adult urethra: instil 5-10 ml in small portions to fill the whole urethra. In order to obtain adequate anaesthesia, several minutes should be allowed to elapse prior to performing urological procedures.

Endoscopy
The instillation of 10-20 ml is recommended for adequate analgesia and a small amount may be applied to the lubricating instrument. When combined with other lidocaine products (e.g. for bronchoscopy), the total dose of lidocaine should not exceed 400 mg.

Proctoscopy and rectoscopy
Up to 20 ml can be used for anal and rectal procedures. The total dose should not exceed 400 mg lidocaine.

Lubrication for endotracheal intubation
About 2 ml applied to the surface of the tube just prior to insertion. Care should be taken to avoid introducing the product into the lumen of the tube.

Contraindications
Known history of hypersensitivity to local anaesthetics of the amide type, or other components of the jelly.

Hypersensitivity to local anaesthetics of the amide type, or to any of the excipients.

Hypersensitivity to methyl and/or propyl parahydroxybenzoate (methyl-/propyl paraben), or to their metabolite para amino benzoic acid (PABA). Formulations of lidocaine containing parabens should be avoided in patients allergic to ester local anaesthetics or their metabolite PABA.

Special warnings and precautions for use
Excessive doses of lidocaine products or short intervals between doses, can result in high plasma levels and serious adverse effects. Patients should be instructed to adhere strictly to the recommended dosage (the management of serious adverse reactions may require the use of resuscitative equipment, oxygen and other resuscitative drugs). (See "Overdose".)

Absorption from wound surfaces and mucous membranes is relatively high and especially high in the bronchial tree. The absorption of lidocaine jelly from the nasopharynx is variable but usually lower than with other lidocaine products. Following instillation in urethra and bladder, absorption is low. Lidocaine jelly should be used with caution in patients with traumatized mucosa and/or sepsis in the region of the proposed application.

The oropharyngeal use of topical anaesthetic agents may interfere with swallowing and thus enhance the danger of aspiration. Numbness of the tongue or buccal mucosa may increase the danger of biting trauma.

When used for endotracheal tube lubrication, care should be taken to avoid introduction of the jelly into the lumen of the tube. The jelly may dry on the inner surface leaving a residue which tends to clump with flexion, narrowing the lumen. There have been rare reports in which this residue has caused the lumen to occlude.

Patients being treated with class III antiarrhythmic drugs (e.g. amiodarone) should be closely supervised, and ECG monitoring should be considered, as the effects on the heart can be additive.

If the dose or administration is likely to result in high blood levels, some patients require special attention to prevent potentially dangerous side effects:
- Patients with partial or complete heart block.
- The elderly and patients in poor general health.
- Patients with advanced liver disease or severe renal dysfunction.

Xylocaine jelly 20 mg/ml is probably porphyrinogenic and should only be prescribed to patients with acute porphyria on strong or urgent indications. Appropriate precautions should be taken for all porphyric patients.

Interactions
Lidocaine should be used with caution in patients receiving agents structurally related to local anaesthetics, since the toxic effects are additive.
Specific interaction studies with local anaesthetics and class III antiarrhythmic drugs have not been carried out, but caution should be observed.
Drugs that reduce the clearance of lidocaine (e.g. cimetidine or betablockers) may cause potentially toxic plasma concentrations when lidocaine is given in repeated high doses over a long time period. Such interactions should be of no clinical importance following short term treatment with lidocaine at recommended doses.

Pregnancy and lactation
Pregnancy
It is reasonable to assume that a large number of pregnant women and women of child-bearing age have been given lidocaine. No specific disturbances to the reproductive process have so far been reported, e.g. no increased incidence of malformations.

Lactation
Like other local anaesthetics, lidocaine may enter the mother's milk, but in such small amounts that there is generally no risk of this affecting the neonate.

Effects on ability to drive and use machines
Depending on the dose, local anaesthetics may have a very mild effect on mental function and may temporarily impair locomotion and coordination.